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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,778	09/18/2003	Alain Goossens	2676-6085US	8721
24247 7550 09/22/2008				
TRASK BRITT				
P.O. BOX 2550				
SALT LAKE CITY, UT 84110				
EXAMINER				
KALLIS, RUSSELL				
ART UNIT		PAPER NUMBER		
1638				
NOTIFICATION DATE		DELIVERY MODE		
09/22/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

Office Action Summary

Application No.

10/666,778

Applicant(s)

GOOSSENS ET AL.

Examiner

RUSSELL KALLIS

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 15-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Claims 1-13 and 15-24 are pending and examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3, 10-13, and 16-19 are rejected under 35 U.S.C. 103(a) as obvious over Muhitch, M. *et al.* Plant Science, 2000, Vol. 157, pp. 201-207 in view of itself is withdrawn in view of Applicants' amendment.

Claim Rejections - 35 USC § 102

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Jasinski M. *et al.* Bulletin de la Societe Royale des Sciences de Leige; 1999, Vol. 68, No. 5-6 p. 323; in light of Jasinski M. *et al.* The Plant Cell, May 2001; Vol. 13, pp. 1095-1107 and attached sequence report. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/26/2008. Applicant's arguments filed 6/11/2008 have been considered but are not deemed persuasive.

Applicants assert that their sequence alignment show 89% sequence identity between Jasinski and the instantly claimed SEQ ID NO: 2 and that the specification describes BLAST as a method for calculating sequence identities. This is not found persuasive because Applicant's specification does not point specifically to any one particular method for conducting alignments but rather indicates that several algorithms are available in the art and further does not indicate the BLAST parameters that would enable 89% identity, as such Applicant's remarks concerning Jasinski as prior art appear to be an after thought. Moreover, Applicants' alignment is between a protein and a protein. The attachment, submitted with the prior art reference, is an alignment for

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a DNA encoding a protein and a protein as recited in claim 15. Clearly, Applicants' remarks are not drawn to the claim limitation of 'a DNA encoding a protein' as recited in the claim; and thus Applicants are arguing limitations that are not in the claim and contrary to Applicants' assertions the reference has all the limitations of Claim 15. The following describes the search parameters used in the alignment:

```
GenCore version 5.1.9
Copyright (c) 1993 - 2006 Bioceleration Ltd.

OM protein - nucleic search, using frame_plus_p2n model

Run on:      June 18, 2006, 09:11:12 ; Search time 18313 Seconds
              (without alignments)
              7463.966 Million cell updates/sec

Title:       US-10-666-778-2
Perfect score: 7399
Sequence:    1 MEPSDLNFRGRSMRGMRG.....AVVFAFTFALGIKAFNFQRR 1425

Scoring table: BLOSUM62
               Xgapop 10.0 , Xgapext 0.5
               Ygapop 10.0 , Ygapext 0.5
               Fgapop  6.0 , Fgapext  7.0
               Delop  6.0 , Delext   7.0

Searched:    6366136 seqs, 31973710525 residues

Total number of hits satisfying chosen parameters: 12732272
Minimum DB seq length: 0
Maximum DB seq length: 2000000000

Post-processing: Minimum Match 0%
                  Maximum Match 100%
                  Listing first 45 summaries

Command line parameters:
-MODEL=frame+ p2n.model -DEV=xlh
-
Q=/abss/ABSSWEB_spool/US10666778/runat_16062006_113353_3122/app_query.fasta.1
-DB=GenEmbl -QFMT=fastap -SUFFIX=p2n.rge -MINMATCH=0.1 -LOOPCL=0 -LOOPEXT=0
-UNITS=bits -START=1 -END=-1 -MATRIX=blosum62 -TRANS=human40.cdi -LIST=45
-DOCALIGN=200 -THR_SCORE=pct -THR_MAX=100 -THR_MIN=0 -ALIGN=15 -MODE=LOCAL
-OUTFMT=pto -NORM=ext -HEAPSIZE=500 -MINLEN=0 -MAXLEN=2000000000 -
HOST=abss02h
-USER=US10666778_CGN_1_1_5548@runat_16062006_113353_3122 -NCPU=6 -ICPU=3
-NO_MMAP -NEG_SCORES=0 -WAIT -DSPBLOCK=100 -LONGLOG -DEV_TIMEOUT=120
-WARN_TIMEOUT=30 -THREADS=1 -XGAPOP=10 -XGAPEXT=0.5 -FGAPOP=6 -FGAPEXT=7
-YGAPOP=10 -YGAPEXT=0.5 -DELOP=6 -DELEXT=7
```

Claim Rejections - 35 USC § 103

Claims 1-13 and 15-19 remain and new claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rea *et al.* WO 98/21938.

The claims are broadly drawn to processes of inducing or enhancing secretion or production of an unspecified secondary metabolite from an unspecified plant or plant cell transformed with a vector comprising a gene encoding an ABC-transporter and selecting thereby; and plants and plant cells thereof. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/26/2008. Applicant's arguments filed 6/11/2008 have been considered but are not deemed persuasive.

Applicant asserts that their definition of enhanced production is separate and distinct from that of enhanced secretion (response pages 16-17). However, a complete reading of the quoted paragraph 0043 from Applicants' specification indicates that the two terms production and secretion can be equivalent in their meaning see underlined portion of paragraph 0043. When a metabolite is sequestered away from the cytosol it is protected from oxidation and thus the secretion to the vacuole will result in enhanced production as recited in the claim and thus the Rea reference does teach indeed this process and thereby reads upon the instantly claimed invention of claims 1-13 and 15-19.

[0043] By the term "to enhance the production" it is meant that the level of one or more metabolites may be enhanced by at least 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90% or at least 100% relative to the untransformed plant which was used to transform with an expression vector comprising an expression cassette further comprising a gene coding for a transporter or an ABC-

transporter. An enhanced production of a secondary metabolite can result in a detection of a higher level of secondary metabolites in the plant, for example in the vacuole. In another embodiment, the enhanced production of at least one secondary metabolite leads to an enhanced secretion. In yet another embodiment, the same production of at least one secondary metabolite occurs in the transformed plant but an enhanced secretion of at least one secondary metabolite occurs by the transformed plant. Secondary metabolites can for example be efficiently produced by continuous secretion from the roots of hydroponically grown plants. This process of secretion is also been termed 'rhizosecretion'.

Applicants' assertion that the Rea reference teaches away for the same reasons as the Muhitch reference is not well founded because the Rrea reference teaches the transport of an indigenous plant compound whereas in Muhitch, it is taught that the compound is a xenobiotic compound.

Claims 1-13 and 15-19 remain and new claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Theodoulou F. *Biochemica et Biophysica Acta*; 2000, 1465, pp. 79-103 in view of Dudler R. *et al.* *Journal of Biological Chemistry*; 25 March 1992, Vol. 267, No. 9 pp. 5582-5888 in further view of Sidler M. *et al.* *The Plant Cell*, October 1998; Vol. 10, 1623-1636. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/26/2008. Applicant's arguments filed 6/11/2008 have been considered but are not deemed persuasive.

Applicants' assertions concerning Dudler Sidler and what is taught with respect to the *atpgp1* gene product fails to respond to the Examiners rebuttal in the previous office action

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namely that one of ordinary skill would have read the results of the Sidler and understood that auxin could also have been the secondary metabolite common knowledge in the field. Further, the remarks supra directed to the definition of enhanced production and enhanced secretion are included here in response to Applicants' remarks directed toward this rejection.

No claim is allowed.

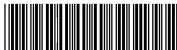
Claims 20-21 are objected to as being dependent upon rejected base claim 15, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Russell Kallis/
Primary Examiner of Art Unit 1638
January 31, 2008

Application Number**Application/Control No.**

10/666,778

**Applicant(s)/Patent under
Reexamination**

GOOSSENS ET AL.

Examiner

RUSSELL KALLIS

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